

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
ENVIRONMENTAL HEALTH LABORATORY BRANCH
BLOOD LEAD PROFICIENCY ASSURANCE PROGRAM
Telephone (510) 620-2876 FAX: (510) 620-2825

A BRIEF DESCRIPTION OF THE PROGRAM

The Childhood Lead Poisoning Prevention Acts of 1986 and 1991 (California Health and Safety Code Sections 124125 et seq. and 105275 et seq., respectively) require the California Department of Public Health (CDPH), formerly the California Department of Health Services, to designate laboratories qualified to do blood lead testing for the CDPH Childhood Lead Poisoning Prevention Branch (CLPPB) or for any blood lead testing reimbursed through the California Department of Health Care Services (DHCS) Child Health and Disability Prevention (CHDP) program. Qualification of a laboratory requires that it is in compliance with the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 for the subspecialty toxicology, that it is a California licensed clinical laboratory or a California approved public health laboratory or holds other licensure or approval designated by DHS Laboratory Field Services (LFS) as equivalent, and that it is judged proficient in blood lead analysis by the CDPH Environmental Health Laboratory Branch (EHLB). Laboratories located outside of the State of California should contact LFS at (510) 873-6327 for information concerning clinical laboratory licensing or approval requirements.

A laboratory's proficiency rating for blood lead testing is based on a review of its performance in one of the blood lead proficiency testing programs recognized by EHLB. Recognized programs are currently the College of American Pathologists Blood Lead Survey (CAP), the Blood Lead Proficiency Testing Regulatory 5-sample HCFA-approved Program offered by the Wisconsin State Laboratory of Hygiene in cooperation with the U.S. Public Health Service Maternal and Child Health Bureau and the Centers for Disease Control and Prevention (WSLH), the State of New York Department of Health Blood Lead Proficiency Test Survey (NYS), and the American Academy of Family Physician's Proficiency Testing program (AAFP-PT). CLIA certification requires participation in a proficiency testing program approved by the Center for Medicare and Medicaid Services (CMS) as meeting CLIA standards. To keep our program consistent with these national standards of laboratory certification, we use only HCFA approved proficiency testing programs.

EHLB evaluates each laboratory's proficiency in blood lead analysis based on its performance in only one proficiency testing program for each four-month CBLPAP Evaluation Period. A laboratory that subscribes to more than one of the recognized proficiency testing programs must inform EHLB of its choice of proficiency testing programs to be used for the proficiency evaluation in advance of the first CBLPAP Evaluation Period for which it is evaluated. A laboratory may request to change the proficiency testing program used for its proficiency evaluation at any time by notifying EHLB of its preference in writing and making whatever arrangements are necessary for EHLB to have access to that laboratory's reported analytical results from the selected proficiency test provider. Any such changes will become effective for the next CBLPAP

Evaluation Period following receipt of the notification by EHLB, provided that all reporting requirements for the change have been met before the end of the current CBLPAP Evaluation Period. It is the responsibility of each laboratory to ensure that its blood lead proficiency test results are reported to EHLB by the laboratory's chosen proficiency test provider in a timely fashion. Missing or unreported proficiency testing results may be considered unsatisfactory performance for the purpose of determining that laboratory's proficiency rating.

To maintain the integrity of the CBLPAP evaluations, EHLB reviews copies of each laboratory's proficiency test results transmitted from the proficiency test providers to EHLB. Subscribers to the CAP Blood Lead Survey must request that CAP send a copy of their Blood Lead Survey results to the State of California. This request must be made by the participating laboratory following the procedure specified in the CAP Surveys Manual. A laboratory wishing to be evaluated on their performance in the WSLH Regulatory 5-sample HCFA-approved Program must notify WSLH that a copy of their blood lead results should be sent to the State of California. Participants in the NYS Proficiency Testing Program must supply EHLB with their NYS laboratory code so that we can locate their test results in the appropriate Blood Lead Proficiency Testing reports. Participants in the AAEP-PT blood lead program must request results be sent to the California Blood Lead Program as well as California Laboratory Field Services.

A list of laboratories evaluated as proficient in blood lead testing is prepared by EHLB three times a year. A summary of the criteria used to evaluate the performance of participating laboratories is enclosed with this letter. EHLB does not certify laboratories to do occupational blood lead testing. That certification is obtained through U.S. Department of Labor, Occupational Safety & Health Administration (OSHA).

Each laboratory participating in CBLPAP is notified by letter of its status when a new list of proficient laboratories is released. A new list of proficient laboratories is released after all proficiency test reports for participating laboratories for an Evaluation Period have been received by EHLB from recognized proficiency test providers and when those results have been evaluated by EHLB according to CBLPAP standards and reports of those evaluations have been generated by EHLB. A new Laboratory joining CBLPAP is notified of its status along with all other participating laboratories. This will occur after proficiency test reports representing one complete CBLPAP Evaluation Period for the applicant laboratory have been received by EHLB from a recognized proficiency test provider, after those results have been evaluated by EHLB according to CBLPAP standards, and after reports of those evaluations have been generated by EHLB and a new list of proficient laboratories is released. A laboratory must be currently designated as proficient in blood lead analysis by EHLB and must appear on the most recent list of proficient laboratories to do blood lead testing for programs administered by CLPPB or reimbursed through CHDP.

Lead exposure is a condition that is reportable to the State of California. Please contact Childhood Lead Poisoning Prevention Branch (CLPPB) at (510) 620-5600 for details about reporting requirements for blood lead results.

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**A SUMMARY OF THE CBLPAP PROFICIENCY CRITERIA FOR BLOOD LEAD
ANALYSIS**

1. A laboratory participating in the California Blood Lead Proficiency Assurance Program (CBLPAP) is considered proficient in blood lead analysis if at least 80% of its evaluated proficiency test results as reported to EHLB by the proficiency test provider are rated satisfactory by the California Department of Public Health (CDPH) Environmental Health Laboratory Branch (EHLB) for at least two out of the three most recent consecutive four-month Evaluation Periods. For laboratories evaluated on the basis of the College of American Pathologists (CAP) Blood Lead Survey, only their test results for specimens formally evaluated by CAP are considered by EHLB for the CBLPAP evaluation. For laboratories evaluated on the basis of the WSLH Regulatory 5-sample HCFA-approved Program, only their test results for specimens for which consensus is attained are considered by EHLB for the CBLPAP evaluation.
2. A new laboratory joining the program is considered proficient if a satisfactory rating is attained on at least 80% of its proficiency test results, as reported to EHLB by the proficiency test provider and as evaluated by EHLB, either for the initial Evaluation Period or for one of the two most recent Evaluation Periods, when two have been completed. A laboratory is considered new to our program until it has completed three Evaluation Periods.
3. A participating laboratory is considered nonproficient and removed from the list of proficient laboratories if it fails to attain a satisfactory rating on at least 80% of its test results, as reported to EHLB by the proficiency test provider and as evaluated by EHLB, for two out of three consecutive Evaluation Periods.
4. A laboratory that has been rated nonproficient and removed from the list of proficient laboratories will be considered proficient and restored to the list only after it has attained a satisfactory rating on at least 80% of its test results, as reported to EHLB by the proficiency test provider and as evaluated by EHLB, for each of two consecutive Evaluation Periods.
5. An individual proficiency test sample result is judged satisfactory if the reported value is within 10% of the target value for samples with lead concentrations greater than 40 µg/dL and plus or minus 4 µg/dL for samples with lead concentrations equal to or less than 40 µg/dL.

Participating laboratories are evaluated triannually. A report of the evaluation is sent to each laboratory and an updated list of proficient laboratories is released for each four month Evaluation Period after all of the participating laboratories' results have been received by and evaluated by EHLB as summarized above and as defined in other communications to the laboratories. A laboratory must be currently designated proficient in blood lead analysis by this proficiency assurance program and must appear on the most recent list of proficient laboratories to do any blood lead testing for any program administered by the CDPH Childhood Lead Poisoning Prevention Branch (CLPPB) or any blood lead testing which is reimbursed through the California Department of Health Care Services, Child Health and Disability (CHDP) program.